DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2015

Viora Ltd.
Omri Kesler
Chief Operating Officer
3 Maskit Street
4673303 Herzliya
Israel

Re: K150035
Trade/Device Name: V10 system
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX, ISA
Dated: March 31, 2015
Received: April 2, 2015

Dear Mr. Kesler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150035

Device Name
V10 system

Indications for Use *(Describe)*
The Viora V10 system is intended for dermatological procedures.

The V-ST Handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The V-Form Handpiece (with BC and FC applicators) is indicated for delivering non thermal RF combined with massage:
• relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and
• temporary reduction in the appearance of cellulite.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Viora Ltd. 3 Maskit Street Herzliya, Israel 4673303 Israel
Contact Person:	Omri Kesler COO Email: omri@vioramed.com Phone Number: +972 9955 1344 Fax Number: +972 9955 1345
Establishment Registration Number:	3005695724
Date Prepared:	May 01, 2015
Device Trade Name(s):	**V10 system**
Device Common Name:	Multi application RF device
Classification:	**Name:** Electrosurgical cutting and coagulation device and accessories **Product code:** PBX, ISA **Regulation No:** 21CFR878.4400, 21 CFR 890.5660 **Class:** II **Panel:** General and plastic surgery devices
Predicate Device(s):	Viora V20 system (K142093) Viora Reaction™ system (K090221)

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Device description

The Viora ***V10 system*** is a RF multi application platform with two available treatment Handpieces:

- **V-ST Handpiece** - Bi-polar radiofrequency (RF) Handpiece.
- **V-Form Handpiece** (with BC and FC applicators) – mechanical vacuum massage and Bi-polar radiofrequency (RF) Handpiece.

The Main Unit (console) provides the operational and safety function of the system. The operator can modify the treatment parameters to achieve specific tissue effects depending on individual patient's skin condition and anatomical structure.

Intended use and indication for use statement

The Viora ***V10 system*** is intended for dermatological procedures.

The **V-ST Handpiece** is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The **V-Form Handpiece (with BC and FC applicators)** is indicated for delivering non thermal RF combined with massage:

- relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and
- temporary reduction in the appearance of cellulite.

Predicade Devices

Substantial equivalence to the following predicate devices is claimed:

Device name	**510k No.**	**Date of Clearance**
Viora V20 system	K142093	November 14, 2014
Viora Reaction™ system	K090221	July 1st, 2009

Substantial Equivalence to Predicate Device

The V10 system console has similar technological characteristics as the predicate device, performance data demonstrate that the differences between the V10 console and the predicate do not raise any new questions of safety and effectiveness.

The Viora V10 V-ST Handpiece has the same intended use, the same technological features and the same performance characteristics as the cleared Viora V20 V-ST Handpiece (K142093). The Viora V10 V-Form Handpiece (with BC and FC applicators) and the Viora ReactionTM B-contour and F-contour applicators (K090221) have identical intended use and similar technological features. Any differences in the V-Form Handpiece design do not raise any new questions of safety and effectiveness, as verified by performance testing.

Therefore, the V10 system is substantially equivalent to its predicate devices.

Performance standards

The ***V10 system*** complies with:

- **IEC 60601-1**: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
- **IEC 60601-1-2**: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests.
- **IEC 60601-2-2:** Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories.

Performance Bench Tests

Bench testing demonstrated that the ***V10 system*** is as safe and effective as the cleared predicate devices.

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Pre-Clinical and clinical study

Since the technological parameters of the Viora ***V10 system*** are well within the previously cleared Viora V20 (console and V-ST Handpiece) and Reaction (B-contour and F-contour applicators) systems, Viora believes that animal and clinical studies are not required to determine the safety and efficacy of the ***V10 system.***

Conclusion

Based on the technological characteristics of the devices and the intended use, Viora believes that the ***V10 system*** and the predicate devices are substantially equivalent. The differences do not raise any new issues of safety or effectiveness.